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September 9, 2009

Via Email and Hand Delivery

Hon. Shira A. Scheindlin
United States District Judge
U.S. District Court, Southern District of New York
500 Pearl Street
New York, New York 10007

Re: *City of New York v. ExxonMobil*, 04 CV 3417 (SDNY)
Motion to Strike Testimony of Dr. Sandra Mohr

Dear Judge Scheindlin:

The City moves to strike the expert testimony of Exxon's witness Dr. Sandra Mohr as unreliable, unsupported by scientific evidence, and beyond the scope of her expert report and deposition. Her opinions that MTBE is not carcinogenic in humans and that neither mutagenicity nor DNA adducts bear any relevance to human disease are contrary to existing science and contrary to the documents she cited as evidence. Other parts of her testimony were also demonstrably false.

Under Rule 702 of the Federal Rules of Evidence, the testimony of an expert must be based on "scientific knowledge" and is admissible only where (1) the testimony is based upon sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the witness has applied the principles and methods reliably to the facts of the case. Fed. R. Evid. 702; *see Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 595 (1993).

"[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos v. National R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002). Because the opinions Dr. Mohr testified to at trial were not supported by adequate scientific foundation, those opinions are unreliable, inadmissible, and must be excluded. Therefore, the City requests that Dr. Mohr's testimony be stricken from the record and that the jury be instructed to disregard her testimony.

DR. MOHR'S TESTIMONY IS NOT SUPPORTED BY THE LITERATURE SHE RELIED ON AT TRIAL AND SHOULD BE STRICKEN FROM THE RECORD

At trial, Dr. Mohr offered opinions on the mutagenicity and carcinogenicity of MTBE that were both beyond the scope of her report and without a solid foundation in the scientific literature on which she purported to rely. Her direct testimony, excerpts of which are attached hereto as Exhibit 1, included the following statements:

- "I have an opinion that MTBE is not carcinogenic in humans." (Trial Transcript ("TT") 3087:1)
- Mutagenicity has "[l]ittle to no relevance" to carcinogenicity in humans (TT 3098:15-18), and "little to no relevance in human disease." (TT 3097:23)
- "There are several studies out there looking at DNA adducts, and they do not correlate with disease…" (TT 3108:7-9)

All three of these opinions are unsupported by the literature on which Dr. Mohr purports to rely. Dr. Mohr stated at trial that "[t]here is no human data that MTBE is a carcinogen, and there is very limited animal data." (TT 3055:14-15) But a document on which Dr. Mohr relies, the U.S. EPA's December 1997 Drinking Water Advisory on MTBE (EPA 1997), excerpts of which are attached hereto as Exhibit 2, reviewed the animal data available at the time and concluded that "[t]he carcinogenicity data *support* a conclusion that MtBE poses a potential for carcinogenicity to humans at high doses." (Exhibit 2 at p. 4, emphasis added.) Furthermore, the EPA never said that low doses of MTBE were *not* carcinogenic – it said only that "[t]he data do not support confident, quantitative *estimation of risk* at low exposure due to the limitations described above." (*Id*, emphasis added.)

Dr. Mohr's testimony also referred to the August 2000 Toxicological Review and Criteria for Evaluation of Exposure to Methyl Tert-Butyl Ether in Drinking Water prepared by the New York State Department of Health (NYSDOH 2000), attached hereto as Exhibit 3. But this document does not support the conclusion that MTBE is not carcinogenic either. Instead, the document stated that MTBE had "caused cancer in laboratory animals" (Exhibit 3 at p. iii) and that "the identification and evaluation of the potential human health effects from long-term exposure to MTBE in drinking water are based on the results of animal studies." (*Id.* at p. ii.) The document also concludes that "[w]hether or not MTBE causes cancer in humans is unknown." (*Id.* at 51.) It does *not* conclude that MTBE is not a human carcinogen.

Dr. Mohr also testified at trial that she reviewed New York's Toxicological Review (Exhibit 3) and in particular "the results of testing for genetic effects of MTBE." (*See* TT 3103:22-3104:10.) But the document does not support Dr. Mohr's conclusions about the mutagenicity of MTBE – neither that MTBE "may not be particularly mutagenic at all" (TT 3104:20-21), nor that mutagenicity bears little relevance to carcinogenicity. In fact, the New York report noted particularly that "MTBE induced changes indicative of DNA damage in three of four mutation tests using lymphoid cells . .

. The activity in lymphoid cells is *particularly relevant given the increased incidence of lymphomas/leukemias* in female rats exposed to oral doses of MTBE (Belpoggi et al., 1995, 1998)." (Exhibit 3 at 30, emphasis added.)

The New York report also highlights the lack of support for Dr. Mohr's opinion that DNA adducts are irrelevant. As the report points out, MTBE "was mutagenic the only time it was tested in a *Salmonella* strain (TA 102) with a functioning DNA excision repair system." (Exhibit 3 at 30). "The results support the hypothesis of Williams-Hill and colleagues that the carcinogenic activity of MTBE may be dependent upon a functional excision repair system *that attempts to remove alkyl adducts* and/or oxidative base damage caused by direct interaction of MTBE or by its metabolites with DNA." (*Id.*) In other words, experimental research supports the theory that MTBE causes cancer by causing genetic mutations that are mediated by the formation of DNA adducts.

The two Chinese studies Dr. Mohr referred to on the stand (TT 3106:1-3107:24) also contradict Dr. Mohr's opinion as to the relevance of DNA adducts. The 2007 study by Yuan et al., included as Tab 18 in ExxonMobil's binder of demonstratives used during Dr. Mohr's examination (and attached hereto as Exhibit 4), explains that "in most cases *DNA adduct level is positively correlated* with the genotoxicity and hence the carcinogenicity of the chemicals (Ottender and Lutz, 1999)." (Exhibit 4 at p. 634, emphasis added.) The 2005 study by Du et al., included as Tab 19 in ExxonMobil's binder (and attached hereto as Exhibit 5), explains that "[w]hen genotoxicity assays and carcinogenicity experiments of a chemical show an inconsistent combination of positive and negative results, *direct investigation of DNA adduction is necessary or very helpful* for assessing whether the test compound is a genotoxin." (Exhibit 5 at p. 398, emphasis added.) Dr. Mohr claims that studies of DNA adducts "just plain haven't panned out." (TT 3108:15.) But there is a vast analytical gap between the evidence Dr. Mohr points to and the conclusions she reaches.

The relevance of DNA adducts to questions of mutagenicity and carcinogenicity is reaffirmed by the U.S. EPA itself, which in its 2005 Guidelines for Carcinogen Risk Assessment (excerpts of which are attached hereto as Exhibit 6) points out that:

> It is *well known* that many carcinogens are electrophiles that interact with DNA, resulting in *DNA adducts* and breakage (referred to in these cancer guidelines as direct DNA effects). Usually during the process of DNA replication, these DNA lesions can be converted into and fixed as mutations and chromosomal alterations that then may *initiate and otherwise contribute to the carcinogenic process* (Shelby and Zeiger, 1990; Tinwell and Ashby, 1991; IARC, 1999). Thus, studies of mutations and other genetic lesions continue to inform the assessment of potential human cancer hazard and in the understanding of an agent's *mode of carcinogenic action.*

Exhibit 6 at p. 2-31, emphasis added.

"[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation-i.e., 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. Contrary to Dr. Mohr's testimony at trial, "[t]he *consensus opinion* (Table 14) is that MTBE is an animal carcinogen because it caused lymphomas/leukemias in female rats, kidney tumors and Leydig cell adenomas in male rats, and hepatocellular tumors in mice." (Exhibit 3 at 31, emphasis added.) Dr. Mohr's opinions that MTBE is not a human carcinogen, that mutagenicity bears little relevance to carcinogenicity, and that DNA adducts have no relationship to human disease are supported by none of the scientific and government agency literature to which she cited in her report or on the stand. Indeed, many of the documents Dr. Mohr relied on state the opposite of her conclusions. The resulting "analytical gap" renders Dr. Mohr's testimony unreliable and inadmissible under *Daubert* as well as *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered").

Dr. Mohr's Statements Regarding FDA Approval of MTBE and the IARC's Classification of MTBE Are False

Dr. Mohr stated during her direct testimony at trial that "MTBE has received experimental approval from the Federal Drug Administration [sic] to use as a medication, as a medication to dissolve gallstones." (TT 3084:8-10.) She also stated in her expert report (attached hereto as Exhibit 7) that MTBE has received FDA approval for use as a human medication to dissolve gallstones (Exh. 7 at 5), a statement demonstrated to be false during Dr. Mohr's cross-examination at trial. (TT 3115:15-22.) "The Food and Drug Administration has *classified*" – not approved – "MTBE as an investigational new drug," (TT 3113:22-25, emphasis added) and did *not* grant approval for use as a human medication. In fact, the FDA defines "investigational or experimental drugs" as "new drugs that have *not* yet been approved by the FDA." (TT 3114:24-3115:1.)

Dr. Mohr also falsely characterized the conclusions reached by the International Agency for Research on Cancer (IARC) and reported in Volume 73 of IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (excerpts of which are attached hereto as Exhibit 8) during her direct testimony. Dr. Mohr was asked, "has IARC classified MTBE as a human carcinogen?" and in response claimed, incorrectly, that "IARC says that MTBE *is not* a human carcinogen." (TT 3096:9-11, emphasis added.) But in fact, IARC concluded that MTBE "is *not classifiable* as to its carcinogenicity in humans," given the limited evidence available at the time of MTBE's carcinogenicity in animals. (Exhibit 9 at p. 375.) The IARC therefore placed MTBE in its Group 3, a category of chemicals for which limited evidence of carcinogenicity is available, rather than in Group 4, which includes chemicals that are *not* carcinogens. (Exhibit 9 at pp. 26-27.)

Because Dr. Mohr's statements about FDA approval of MTBE and IARC's classification of MTBE are demonstrably false, those statements and all related

testimony, should be stricken from the record and the jury should be instructed to disregard them.

Dr. Mohr's Opinions Exceed the Scope of Her Expert Report and Prior Testimony

Dr. Mohr's opinion that MTBE is not carcinogenic in humans is not set forth in her expert report. Her expert report states only that no published reports link increased cancers to MTBE exposures, and that the United States Environmental Protection Agency and International Agency for Research on Cancer have not officially classified MTBE as a human carcinogen. (Exh. 7 at 16.) Nor did Dr. Mohr express this opinion in her 2001 deposition in *South Tahoe Public Utility District v. Atlantic Richfield Company et al.*, excerpts of which are attached hereto as Exhibit 10. Instead, she stated at that time that "while it *does* look like MTBE is a rodent carcinogen, how that's going to translate into potency for humans remains to be seen." (Deposition Transcript 113:8-12, emphasis added.)

Nor is Dr. Mohr's opinion that mutagenicity studies have "[l]ittle to no relevance" to carcinogenicity or any other form of disease in humans set forth in her expert report. Her expert report does not state that mutagenicity is *irrelevant*, but that the U.S. EPA believed in 1997 that "the weight of evidence 'indicated that MTBE is not mutagenic." (Exh. 7 at 17.) In fact, the report went on to say that a more *recent* review of genotoxicity assays stated that "mutagenicity in mouse lymphoma cells" had been independently verified. (Exh. 7 at 18.) At no point in her report does Dr. Mohr make the claim she made at trial: that mutagenicity has no relevance to human disease.

Finally, Dr. Mohr's opinion that DNA adducts do not correlate with disease is not stated in her expert report. Instead, she states only that the study of MTBE and DNA adducts relied upon by Dr. Burns "has been criticized in the way it was conducted" and describes the criticism at issue. (Exh. 7 at 18.) Dr. Mohr did not express opinions about either mutagenicity or DNA adducts in her 2001 deposition.

LEGAL STANDARD

Rule 702 renders the district court responsible for ensuring that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert,* 509 U.S. at 589. In *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 152 (1999), the Supreme Court clarified that, whether a witness's area of expertise was technical, scientific, or more generally "experience-based," Rule 702 requires the district court to serve the "gatekeeping" function of "mak[ing] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."

Expert testimony is subject to Rule 403 as well as Rule 702 and "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Fed.R.Evid. 403. The Second Circuit

has pointed out the importance of both rules in evaluating expert testimony: "the Supreme Court, echoed by members of our own court, has noted the uniquely important role that Rule 403 has to play in a district court's scrutiny of expert testimony, given the unique weight such evidence may have in a jury's deliberations." *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005), citing *Daubert,* 509 U.S. at 595 ("'Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.'" (quoting Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended,* 138 F.R.D. 631, 632 (1991))); *United States v. Young,* 745 F.2d 733, 766 (2d Cir.1984) (Newman, *J.,* concurring) (noting that "the very breadth of the discretion accorded trial judges in admitting [an expert] opinion under Rules 702 and 403 should cause them to give the matter more, rather than less, scrutiny. A trial judge should not routinely admit opinions of the sort at issue here and should weigh carefully the risk of prejudice."). Finally, in assessing the admissibility of expert opinion, the Court must weigh its probative value against the danger of unfair prejudice, confusion of the issues, misleading the jury, or waste of time. *See* Fed. R. Evid. 402.

Thus, under Rules of Evidence 402, 403, and 702 as well as *Daubert,* the district court must determine whether the proposed testimony "both rests on a reliable foundation and is relevant to the task at hand," (*Daubert,* 509 U.S. at 597) and must act as "a gatekeeper to exclude invalid and unreliable expert testimony." *Bickerstaff v. Vassar Coll.,* 196 F.3d 435, 449 (2d Cir.1999); *see Malletier v. Dooney & Bourke, Inc.*, 525 F.Supp.2d 558, 565-566 (S.D.N.Y. 2007). Because Dr. Mohr's testimony is unreliable, its probative value is minimal and is substantially outweighed by its potential for unfair prejudice, confusion of the issues and misleading the jury. In this case, the trial court should serve as that gatekeeper and strike Dr. Mohr's invalid and unreliable expert testimony from the record.

Accordingly, the City respectfully requests that Dr. Mohr's testimony be stricken from the record, and that the jury be instructed to disregard her testimony as to the FDA's purported approval of MTBE, the IARC's classification of MTBE, the non-carcinogenicity of MTBE in humans, the relevance of mutagenicity studies to cancer, and the relative weight of evidence pertaining to DNA adducts.

Respectfully submitted,

Victor M. Sher
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Cc: All Counsel via LNFS & Email

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x
THE CITY OF NEW YORK, et al,

Plaintiffs,

-v- 04 CV 3417

EXXON MOBIL CORPORATION, et al,

Defendants.
----------x

New York, N.Y.
September 1, 2009
10:05 a.m.

Before:

HON. SHIRA A. SCHEINDLIN,

District Judge

APPEARANCES

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have carcinogenic effects.
Q. With regard to that classification system, you reviewed documents as to whether or not MTBE has been classified?
A. Yes, I have.
Q. With respect to the EPA, has it formally classified MTBE in any of those categories?
A. The U.S. EPA has not classified MTBE as a human carcinogen.
Q. With respect to MTBE, the jury's heard testimony about levels of exposure. In your opinion to a reasonable degree of scientific and medical certainty, is there such a thing as a safe level of exposure to MTBE in drinking water?
A. Yes, there is.
Q. Can you tell the jury why.
A. There is no human data that MTBE is a carcinogen, and there is very limited animal data. We don't really think it's much of a carcinogen, if at all. There are some noncarcinogenic effects --
MR. CHAPMAN: Your Honor, is this the witness's testimony? If it is, it should be "I."
THE COURT: Yes, I agree. I was worried about the "we." Let's rephrase that. Can you give your opinion?
THE WITNESS: Yes.
Q. With respect to your opinion --
THE COURT: Hold on.
MR. STACK: I apologize.

Q. With regard to the method that is being used, do you know where that method for dissolving gallstones was developed?
A. I believe it was developed by a Dr. Fischel. I'm not exactly sure -- Mayo Clinic. I could be wrong on that.
Q. With regard to this particular method, have you actually reviewed the literature regarding the procedure that is used to dissolve gallstones?
A. MTBE has received experimental approval from the Federal Drug Administration to use as a medication, as a medication to dissolve gallstones. In Connecticut they used this procedure for quite a while. They have used it in Europe for quite a while for people who could not tolerate surgery. I don't really mean the little laproscopic surgery that they do now. But in the old days, the old days being 20 years ago, when you had gallbladder surgery, sometimes they would make a big scar and you would be off work for six weeks or more.

For people who could not tolerate having gallbladder surgery, another way to get rid of the gallstones is to dissolve them. MTBE was used to dissolve gallstones. There are a couple of different methods. The most common is percutaneous infusion.
Q. What does that mean?
A. You take a needle with a little tube on it, you stick it in, into the gallbladder, and you run the MTBE through in small amounts over a period of a couple hours until the gallstones

A. I have an opinion that MTBE is not carcinogenic in humans.
Q. With regard to the work that you have done, did you review the studies that were performed on animals using inhalation?
A. Yes, I have.
Q. Can you tell the jury what the inhalation studies that you reviewed showed.
A. There are two animal inhalation studies looking at cancer as end points. One by Dr. Chung and also Dr. Berg used rats. The rats were exposed to levels of MTBE at zero -- that's the control group, they didn't get any MTBE -- at 400 parts per million, 3,000 parts per million, and 8,000 parts per million. In those rats that were exposed at 8,000 parts per million -- you have to add three more zeros to get parts per billion. At the highest doses they found an increase -- well, at both doses they found an increase in nephropathy, in kidney disease. But they did find an increase in kidney tumors in male rats at the high doses.
Q. With regard to the other study that was done by Burleigh Flayer, did you review that as well?
A. Yes.
Q. What did that show?
A. The Burleigh Flayer study was done on mice instead of on rats. The mice were exposed to the exact same levels that the rats were exposed to. For 18 months they were exposed to zero, 400, 3,000, or 8,000 parts per million. The mice showed an

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due to chance alone. But statistically significant in this case means they are 95 percent sure that there was an increase in the hepatocellular adenomas, noncancerous liver tumors, or cancerous liver tumors added together in female mice.
Q. In your opinion, do the mice and rat studies using the inhalation mode demonstrate that MTBE is a potent carcinogen which may be carcinogenic to humans?
A. No.
Q. Why not?
A. The levels that were given to the mice and rats, the highest levels are astronomical. They are a huge amount, far more than a human would be ever exposed to. Also, we know that there are some chemicals that are carcinogenic in animals that just aren't carcinogenic in humans. So when we see animal studies, you have to take that sort of in context of what the other data are showing.
Q. In the course of your work on this matter, did you also review studies where animals were exposed to MTBE through ingestion?
A. Yes, I have.
Q. Were those rats or mice in the ingestion study.
A. They were rats.
Q. Who performed that work?
A. The work was done in Italy. The first author on the paper is Balpoggi, or Belpoggi, I guess. They took Sprague Dawley

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rats and exposed them to either no MTBE, 250 milligrams per kilogram of MTBE, or 1,000 milligrams per kilogram of MTBE. They did it by nasal gavage. That means that the rats weren't about to eat that stuff, so they put a tube down in the rat's stomach and force-fed it to them in olive oil.
Q. With regard to the Belpoggi study, have you as part of your professional work assessed that study and its findings?
A. Yes, I have.
Q. What did you find?
A. It's a little hard to know exactly what to make of that paper. If you look at all tumors, clearly in the Belpoggi study the rats that got olive oil alone had lots more tumors than the rats that got MTBE. If you look at just noncancer tumors or cancer tumors. The rats that got the 250 milligrams per kilogram of MTBE had a few less tumors and the rats that got 1,000 milligrams per kilogram of MTBE had lots fewer tumors.
THE COURT: Had what?
THE WITNESS: Fewer tumors, lots fewer tumors.
A. Well, that seems a little odd. But Belpoggi said that female rats had an increase when they added together leukemia and lymphoma, statistically significant increase in leukemia and lymphoma. So you look at the male rats. Leukemia and lymphoma clearly went down in the male rats. The people who got -- people -- the rats that got olive oil alone had the

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also look at government agencies and standard-setting agencies in the health area to see if they had ever determined that MTBE was classified as a human carcinogen?
A. Yes, I have.
Q. Did you look at the work that was done by the Agency for Research on Cancer associated with the World Health Organization, IARC?
A. I have looked at the IARC document.
Q. Tell the jury, has IARC classified MTBE as a human carcinogen?
A. IARC says that MTBE is not a human carcinogen. They do not classify it as a probable human carcinogen.
Q. Have you looked at any of the work that was done by the European Union in determining for European countries whether or not MTBE is a carcinogen?
A. Yes. The European Union also has a group that looks into these kinds of things, and they issued a report. The European Union also says that MTBE is not a probable human carcinogen.
Q. Can you tell the jury what the National Toxicology Program is.
A. The National Toxicology Program is an interagency program within the U.S. federal government consisting of representatives from NIOSH, National Institute of Occupational Safety and Health, NIEHS, the National institute of Environmental Health Sciences, and the toxicology program

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located within the FDA, the Federal Drug Administration. Those three bodies come together and issued a report.
Q. Did the National Toxicology Program in its report classify MTBE as a human carcinogen?
A. The National Toxicology Program did not classify MTBE as a probable human carcinogen.
Q. Is there any standard-setting agency that you've seen in the health field that's classified MTBE as a human carcinogen?
A. No, not that I've seen.
Q. With regard to your opinions in this case based on your research and review of the literature, have you formed an opinion to a reasonable degree of scientific or medical certainty regarding the carcinogenicity of MTBE in humans?
A. Yes, I have.
Q. What is your opinion?
A. My opinion is that MTBE is not a human carcinogen.
Q. In your field as a health professional, can you tell the jury what the phrase "weight of the evidence" means to you.
A. "Weight of the evidence" means how much credibility you give to different kinds of evidence. When I teach my environmental epidemiology class, and we're talking about carcinogenesis, I teach them that mutagenic studies have almost little to no relevance in human disease. The next rung are animal studies. We give some credence to animal studies, although we know that there are some chemicals that cause

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me.
THE WITNESS: I've got it here.
THE COURT: OK.
THE WITNESS: "More recently, 25 genotoxic assays were reviewed, with the author finding the data indicative of genotoxicity are very weak, with none of the studies indicating significant activity having been independently verified except for the mutagenicity in mouse lymphoma cells."
THE COURT: Thank you. The author of that is McGregor?
THE WITNESS: Yes, it is.
THE COURT: Do you know him, by the way?
THE WITNESS: I do not. He is in England.
BY MR. STACK:
Q. In the course of your work, you reviewed the Toxicological Review for the establishment of State of New York's MCL, am I correct?
A. Yes, I have.
Q. If I could direct your attention to tab 6, page 29, table E as in echo. Do you have that table in front of you?
A. Yes, I do.
Q. Did the State of New York, in developing its MCL, also look at and report on the results of testing for genetic effects of MTBE?
A. Yes, it did.

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Q. What did they report in their MCL support document?
MR. CHAPMAN: Your Honor, the document speaks for itself.
THE COURT: Yes, I know. He is asking this expert to summarize it. It may speak for itself, but the jury aren't scientists and neither am I. She is, and we'll hear her explain it.
A. Similarly, the MCL document from the State of New York says the results of 21 of 25 tests to date are negative. That was regarding assays for mutagenicity.
Q. With regard to the weight of the evidence here, what does the weight of the evidence show to you --
THE COURT: It does say on the other hand 4 tests showed positive results, right?
THE WITNESS: Yes, it does.
THE COURT: Go ahead.
Q. As an epidemiologist and a professional in this area, what does the weight of the evidence show concerning the testing results of the mutagenicity of MTBE?
A. The results show that MTBE is at best a weak mutagen and may not be particularly mutagenic at all.
Q. In the context of evaluating the carcinogenicity of MTBE, is it your opinion that the mutagenicity of a substance like MTBE is even a factor in humans?
A. As I think I mentioned, in my environmental epi class,

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Q. Can you tell the jury what the two studies were that you looked at in Chinese. You actually read these reports, correct?
A. I read these two studies. One is by Dr. Du and the other one is by Dr. Yeung, I think. Dr. Du is the fourth author I think on the Dr. Yeung study, so I assume that they did the work in collaboration.
Dr. Du reported from his laboratory in China that he had discovered an MTBE DNA adduct. They had looked under it under mass spectroscopy and in the Yeung paper they had done the same thing with a different type of mass spectroscopy.
MR. CHAPMAN: Your Honor, once again, this is beyond the scope. If your Honor looks at page 18, all it says --
THE COURT: Right, I'm going back to it.
MR. CHAPMAN: All that says is she is reporting what other people said but not coming to an opinion. Just for her to parrot what other people say is not going to --
THE COURT: You are digging a hole here for yourself. I allowed your expert to do precisely that. I'm sure if you read the transcript you will recall that I let her summarize many other studies, and she said that was the basis for her opinion.
MR. CHAPMAN: That is an appropriate testimony. But that's not what was done in her expert report.
THE COURT: It is. She is criticizing Dr. Burns's

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study. She said Dr. Burns relies upon Du, the person she is talking about, citing that MTBE causes DNA adducts. Then she says why this study has been criticized. She doesn't have to come out and say, therefore I criticize Dr. Burns's report. That's what the opinion is. That's obviously the opinion. She is explaining why she criticizes it, that's all. She can't reach her own opinion that she didn't tell you about with respect to mutagenicity, but she can tell you why she criticizes Dr. Burns's approach. It's right there.
MR. CHAPMAN: Thank you, your Honor.
THE COURT: If you would phrase it that way, I'd appreciate it, Mr. Stack.
Q. In the course of your work on this matter, did you critically analyze some of the findings of Dr. Burns relative to her reliance on the Du study?
A. Yes, I did.
Q. What did you do? No pun intended.
A. I had read and reread the papers by Dr. Du, and I think that was the first time that I read the one by Dr. Yeung. They find that MTBE may cause an MTBE adduct. DNA adducts are sort of an old-hat idea that we have had in medicine that you don't have to wait for disease. You can find these markers of disease, predisease if you will, and those are the people that you would spend time screening. It just hasn't panned out.
I think that Dr. Burns said in her testimony that

there have been hundreds of reports with DNA adducts. So on Sunday I went to the --

THE COURT: You mean this past Sunday?

THE WITNESS: This past Sunday.

THE COURT: I can't allow that.

A. All right. I have never seen a single study that shows that DNA adducts are a marker for disease. There are several studies out there looking at DNA adducts, and they do not correlate with disease, which is why for the most part we don't spend much time doing them in medicine anymore. Everything is genomics and snips. I guess now the big thing is single nucleotide polymorphism. We are always trying to find what causes cancer, why does one person get cancer and the other person doesn't, what makes them different. We thought maybe it was DNA adducts, but they just plain haven't panned out.

Q. With regard to DNA adducts and damage to cells in the human body, as a medical doctor, based on your training, tell the jury, what does the human body do with damaged cells.

A. If you have damage to your DNA from any cause, any cause at all, if the cell dies, nothing happens. Cells die all the time. I lose skin cells and hair cells and all kinds of cells all the time. So if damage happens to a cell that's going to die, nothing happens.

If damage happens to a cell that doesn't divide, nothing happens. You increase brain cells until you're about

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Q. Now, you prepared an expert report in this case, correct?
A. Yes.
Q. Now, in your expert report -- it is in the notebook -- you said -- it is on page 5 of the report. You say there "MTBE has received FDA approval for use as a human medication to dissolve gallstones." Do you see that?
A. Yes, I do.
Q. And then on page 8 of your report, you summarize. You say, "MTBE has received FDA approval for use as a human medication to dissolve gallstones."
Now, those statements really aren't accurate, are they?
A. In what way?
Q. The FDA did not approve MTBE for use as a human medication to dissolve gallstones, did it?
A. The FDA gave approval for experimental use of MTBE, but it's not patentable so nobody would ever do all the studies to get full approval.
Q. And you said there in your report that the FDA gave approval. So let's see what the FDA says about it.
Can we go to the next one, please.
Now, here in the Federal Register, which is Tab 1, and it's page 41 of 426, it says: "The Food and Drug Administration has classified MTBE as an investigational new drug." Do you see that?

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A. Yes, I do.
Q. In the Federal Register.
And now let's go to see what the Federal Register says about that.
Can we have the next one, please?
MR. STACK: Your Honor, this is not from the Federal Register.
MR. CHAPMAN: No. Did I say that? It is from the FDA.
MR. STACK: I object. This is not from any federal document.
MR. CHAPMAN: It is from the FDA Web site, your Honor, and therefore it comes in as a government document.
THE COURT: He is representing, he is calling it the FDA's Web site. Mr. Stack, do you want --
MR. STACK: Your Honor, it does indicate it has an FDA.gov and it is a consumer information statement. So I withdraw that.
THE COURT: It is OK.
MR. STACK: It is just not from the Federal Register. It is OK.
THE COURT: Thank you. I appreciate that.
BY MR. CHAPMAN:
Q. Here is what the FDA says: "Investigational or experimental drugs are new drugs that have not yet been

approved by the FDA." Do you see that, Dr. Mohr?
A. Yes.
Q. Now, you are the medical director for an insurance company?
A. Yes, I am.
Q. Are you aware that Aetna Insurance Company does not cover treatment for gallstones because MTBE is not FDA approved? Are you aware of that?
A. You said as a medical director at New York Life?
Q. Yes.
A. No, I am not aware that Aetna doesn't pay for gallstones with MTBE, but I think I did say that it had received experimental approval --
Q. Yes.
A. -- here in court.
Q. Right. But what you said in your report is that it had received FDA approval, and that's not true?
A. I should have said experimental, like I did here in court. I apologize.
Q. You said it twice in your report that it was FDA approved, right?
A. Well, twice but it is cut and pasted. It is the same thing.
Q. It is a different type. Do you want to see it again?
A. Of course it is a different type. All of the things on the conclusion page are cut and pasted from the text. So it's

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says; do you see that?
A. All right.
Q. Let's go to the next page.
And this study included people from the National Institute of Environmental Health Sciences. Do you know what that is?
A. Yes, I do.
Q. What is it?
A. If you've heard of the National Institutes of Health, there are lots of different National Institutes of Health, like there is a Cancer Institutes of Health, and NIEHS, the National Institute for Environmental Health Sciences, is one of those institutes.
Q. And you testified that you knew what the Centers for Disease Control and Prevention is, right?
A. Yes, I do.
Q. That is a national public health organization?
A. Yes, it is.
Q. And you know what the United States Environmental Protection Agency is?
A. Yes.
Q. Let's go to the next page.
And here is what representatives of all of those organizations had to say. They say there "We believe the weight of evidence supports regarding MTBE as having a

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carcinogenic hazard potential for humans."
Do you see that?
A. Yes, I do.
Q. And you disagree with that?
A. In 1997 I might have agreed with that; but now that I know about the problems with the Belpoggi study and the Belpoggi labs, I do not agree with that.
Q. So because you think there are problems with one of those three studies, you have changed your opinion?
A. Yes, I have.
Q. OK. And so if there were just two inhalation studies that came out the way they did, that would be not enough evidence to reach the conclusion that's in yellow; you needed three, is that right?
A. Well, because the tumors in male rats occur with any kind of branch chain hydrocarbon, including those that we know are noncarcinogenic, it's hard to put too much faith in that particular tumor. And because the hepatocellular adenomas are noncarcinogenic, yeah, I think that you needed a little bit more weight of evidence. And the weight of evidence in '97 -- Mary White came to this conclusion. I know her. We are friends. I respect her. In '97 she might have been able to get me to agree with that statement, but now that we know, we have more information, I do not.
Q. And how many more of these cancer studies has the petroleum

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Drinking Water Advisory: Consumer Acceptability Advice and Health Effects Analysis on Methyl Tertiary-Butyl Ether (MtBE)

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